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510(k) Summary of Substantial Equivalence

Pursuant to §513(i)(3)(A) of the Food, Drug, and Cosmetic Act, Mitek Worldwide is required to submit with this Premarket Notification either an "...adequate summary of any information respecting safety and effectiveness or state that such information will be made available upon request of any person." Mitek Worldwide chooses to submit a summary of information respecting safety and effectiveness. According to §513(i)(3)(B), "Any summary under subparagraph (A) respecting a device shall contain detailed information regarding data concerning adverse health effects..."

1. MANUFACTURER:

Mitek Worldwide
A division of Ethicon
A Johnson & Johnson Company
249 Vanderbilt Avenue
Norwood, MA 02062

Contract: Karen K. Sylvia, Manager, RA
Date Prepared: 15 July 2003

2. DEVICE:

Trade name:	Bio-INTRAFIX Tibial Tapered Screws and Sheaths
Classification Name:	Fastener, Fixation, Biodegradable Soft Tissue
Product Code:	MAI
Classification:	888.3040
Common Name:	Orthopedic Screw, Fixation Device

3. PREDICATE DEVICE:

The predicate devices used to determine substantial equivalence for the Mitek's Bio-INTRAFIX Tibial Screw and Sheaths are IntraFIX (K983560) and Biocryl Interference Screws (K013572) currently marketed by Mitek Worldwide, Norwood, MA 02062.

4. DEVICE DESCRIPTION:

The Mitek Bio-INTRAFIX Tibial Screw and Sheath is an absorbable fixation implant for the repair of soft tissue grafts during ligament reconstruction. Bio-INTRAFIX is a two-part system designed to fixate soft tissue to bone for ligament reconstruction.

5. INTENDED USE:

The Bio-INTRAFIX Tibial Screw and Tibial Sheath are intended for fixation of soft tissue grafts during cruciate ligament reconstruction.

6. Safety and Performance:

The determination of substantial equivalence for this device was based on a detailed device description, conformance to consensus standards and voluntary standards.

Based on the indications for use, technological characteristics, and comparison to predicate devices, the Mitek Bio-INTRAFIX Tibial Screw and Sheath have been shown to be substantially equivalent to predicate devices under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 15 2003

Ms. Karen K. Sylvia
Regulatory Affairs Manager
Mitek Worldwide
249 Vanderbilt Avenue
Norwood, MA 02062

Re: K032167
Trade/Device Name: Bio-INTRAFIX Tibial Tapered Screw and Sheath
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: July 15, 2003
Received: July 21, 2003

Dear Ms. Sylvia:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) K032167

Device Name ***Bio-INTRAFIX Tibial Screw and Sheath***

Indications for Use

The Bio-INTRAFIX Tibial Tapered Screw and Sheath are indicated for fixation of soft tissue grafts during cruciate ligament reconstruction.

(Please do not write below this line - Continue on another page if necessary)
Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K032167

Prescription Use Yes
(Per 21 CFR § 801.109)

OR

Over-the-Counter Use No

(Optional Format 1-2-96)